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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,945	07/22/2003	Edward T.H. Yeh	UTSH:245USC1	2419

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Gina N. Shishima
Fulbright & Jaworski L.L.P.
Suite 2400
600 Congress Ave.
Austin, TX 78701

EXAMINER	
MOORE, WILLIAM W	
ART UNIT	**PAPER NUMBER**
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/624,945	YEH ET AL.	
	Examiner	Art Unit	
	William W. Moore	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-51,53-55,57-60 and 66-68* is/are pending in the application.

4a) Of the above claim(s) *51,66 and 67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-50,53,55,57-60 and 68* is/are rejected.

7)☒ Claim(s) *54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection on 3 August 2007. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3 August 2007 has been entered, amending claims 45 and 55 to remove the functional limitation "sentrin-specific protease", amending claim 63 to remove the designation "SENP1", canceling claims 56, 64, and 65, and adding the new claims 66-68. Claims 1-44, 52, 61 and 62 have already been canceled, thus claims 45-51, 53-55, 57-60 and 66-68 remain in the application. This communication is not made final because new grounds of rejection are stated below.

Maintenance of Restriction Requirement of Record for Groups II and IV

New claims 66 and 67 describe, verbatim, subject matters of previously-cancelled claims 64 and 65, thus are identically directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 66 and 67 are claims of Group IV of the restriction requirement mailed 12 June 2006 not elected for prosecution by Applicant in the Election made 12 July 2006 wherein Applicant elected, without traverse, the invention of Group I wherein claims 45-50 are drawn in part to, and claims 52 and 55-63 are particularly drawn to, a protease comprising all or part of SEQ ID NO:2. Applicant has already received an action on the merits for the originally presented and elected invention of Group I. Accordingly, just as claims 64 and 65 were withdrawn from consideration in the communication mailed 23 February 2007 as directed to a non-elected invention, claims 66 and 67 are now withdrawn from consideration herein as being directed to a non-elected invention.

In addition, as explained in the communication mailed 23 February 2007, claims 45-50 and the new claim 68, drawn in part to polypeptides comprising fragments of SEQ ID NO:8, and claim 51 drawn particularly to a specific fragment of SEQ ID NO:8, are an invention of the non-elected Group II, thus claims 45-50 and the new claim 68 remains withdrawn in part from, and claim 51 remains entirely withdrawn from, consideration herein as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Rescission of Restriction Requirement of Record for Group III

The Restriction Requirement of Record as between the elected invention of Group I and the non-elected invention of Group III is hereby RESCINDED. Prior art affecting claim 53

particularly drawn to, as well as claims 45-50 and 68 drawn in part to, the invention of Group III is identified and applied to the claims representing, in part or entirely, the invention of Group III.

Objection of Record Maintained: Non-Elected Subject Matter

Claim 54 remains objected to herein, and claims 45-50 and the new claim 68 are objected to in part, because the claims are not amended to remove recitations of non-elected subject matter of Group II, i.e., the polypeptides of SEQ ID NO:8. Applicant's argument at page 4 of the Response filed 3 August 2007 that claims 45 and 54 should be considered "proper linking claims" has been considered but is not persuasive because Applicant chose not to elect the subject matter of Group II in the Election made 12 July 2005. As noted in the communication mailed 23 February 2007, removing recitations of non-elected subject matter from claim 54 will make claims 54 and 63 substantial duplicates, one of the other.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-50 are rejected, and the new claim 68 is rejected, essentially for reasons of record, under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants argument at pages 5 and 6 of the Response filed 3 August 2007 have been fully considered but they are not persuasive. Applicant suggests that the formula of claim 45 finds support in a sentence spanning pages 31 and 32 of the specification but this statement of multiple, indistinct, genera fails to identify or suggest the set of six octapeptides selected, *de novo*, by Applicant well after the filing dates of the original US priority document and US parent application. A suggestion of indistinct, overlapping, genera cannot be considered to constitute the disclosure of a select set of only six species, nor is there any other disclosure of "relevant identifying characteristics" – according to the decision in *Regents of the Univ. of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir.1997) – that is sufficient to reasonably convey to one skilled in the relevant art by, e.g., some teaching, suggestion, or hint that the inventors had appreciated that the set of six peptides first formulated in the claims presented on 22 July 2003 could define a polypeptide of the claimed invention at the time the application was filed.

Claims 45-50, 55, and 57-60 are rejected, and the new claim 68 is rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for preparing and using a sentrin-specific protease comprising an amino acid sequence of, at least, the carboxyl-terminal 200 amino acids of SEQ IDs NOs:2 and 10,

does not reasonably provide enablement for the use of generic peptides and polypeptides comprising progressively larger regions of 8 to 200 amino acids selected arbitrarily from the amino acid sequences of SEQ IDs NOs:2 and 10 that either (i) have, internally or at either terminus, a peptide that conforms to the formula of claim 45, in the case of claims 45-50, or (ii) have no particular structural feature, in the case of claims 55 and 57-60, and diverge elsewhere from SEQ IDs NOs:2 or 10 by amino acid substitutions, deletions and/or insertions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant's argument at pages 5 and 6 of the Response filed 3 August 2007 have been fully considered but they are persuasive only with respect to enablement as to making. Applicant suggests that no undue experimentation would be required of one skilled in the art to use the peptides and polypeptides for making antibodies. There is no doubt that the integral amino acid sequence of SEQ ID NO:2 can be made and permitted to fold properly in order to present authentic antigenic epitopes that would permit one skilled in the art at the time the invention was made to raise antibodies having a specific and substantial utility, i.e., the ability to recognize and bind to the sentrinase of SEQ ID NO:2 that itself has a specific and substantial utility. Where the specification discloses at least one useful embodiment within the scope of claims 45-50, 55, and 57-60 rejected herein, a polypeptide of claim 63 not subject to this rejection, no rejection is made under 35 U.S.C. § 101 for lack of utility. The specification does not enable the use by the artisan or the public of the indistinct genera described by the rejected claims because it fails to teach the artisan how to select from the myriad peptides and polypeptides within the scope of the claims anything, other than SEQ ID NO:2 itself, with which to raise an antibody that can recognize either a disclosed sentrin-specific protease of SEQ ID NO:2 or anything in particular. Instead, the specification suggests only that an "empirical approach", see the paragraph pages 25-26 of the specification, combined with the teachings at pages 40-46 of the specification might result in random selection of a claimed generic peptide or polypeptide according to either from regions of SEQ ID NO:2 in the case of claims 55 and 57-60, or comprising an octapeptide of claim 45 somewhere within them in the case of claims 45-50. Such an empirical approach cannot provide one skilled in the art with a secondary structure, let alone a tertiary structure, that resembles the native tertiary structures of the integral SEQ IDs NOs:2 and 10 sufficient to provide an authentic antigenic epitope permitting use of the antibody. Absent any meaningful guidance in the specification, and none can be found, the proposed enablement as to use falls well short of the standard set by the CCPA, the precursor of the Court of Appeals for the Federal Circuit, which is not to "make and screen" any and all possible alterations because a

reasonable correlation must exist between the scope asserted in the claimed subject matter and the scope of guidance the specification provides. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 25 (CCPA 1970). The Federal Circuit approved this standard set by the CCPA in *Genentech, Inc. v. Novo-Nordisk A/S*, 42 USPQ2d 1001 (Fed. Cir. 1997). The specification provides no guidance commensurate in scope with Applicant's proposed, empirical, selection of a useful epitope from the myriad portions of the amino acid sequence of SEQ ID NO:2 embraced by claims 45-50, 55, and 57-60 that is capable of presentation to the immune defense system of an animal in order to raise antisera that will recognize the integral, and useful, sentrin-specific proteases of SEQ IDs NOs:2 and 10.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 45-50, 53, and 68 are rejected under 35 U.S.C. § 102(e) as being anticipated by Hillman et al. US 2002/0106373, made of record in herewith.

Hillman et al. disclose a polypeptide comprising the octapeptide sequence PIHLEVHW that is present within the sequence of amino acids from position 19 through position 332, inclusive, of their SEQ ID NO:3 that is entirely identical to the amino acid sequence of SEQ ID NO:10 herein from position 255 through position 568, inclusive, meeting the limitations of claims 45-50, 53 and 68 herein. See the sequence comparison accompanying this communication.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. §§ 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 55, 57, and 58 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the human cDNA clone IMAGE:684275 having the GenBank Accession No. AA236084 and published in 1997 by the Cancer Genome Anatomy Project of the National Cancer Institute, already of record, in view of Edwards et al., US 6,222,029, made of record herewith.

Applicant's arguments in the Response filed 3 August 2007 with respect to claims 55, 57, and 58 have been considered but are moot in view of the new ground(s) of rejection. Applicant suggests that the disclosure of the nucleic acid sequence of the human cDNA in GenBank Accession No. AA236084 cannot be prior art because more than one amino acid sequence may be deduced from the nucleotide sequence of the cDNA. Claims 55, 57 and 58 do not require that a "comprising" polypeptide have any particular size, that it commence with any particular amino acid, or that it have any particular carboxyl terminal amino acid and, indeed, require no more than sequence identity with any 25, or 50, or 100, contiguous amino acids somewhere within SEQ ID NO:2. Edwards et al. demonstrate that at the time the invention was made it was (i) routine to determine the longest continuous open reading frame, and the deduced amino acid sequence thereof, from the six potential open reading frames available in any human EST, and that it was also (ii) routine to exclude from consideration ESTs generated from transcripts isolated from human tissues that correspond to (a) non-coding nucleic acid sequence elements such as tRNAs, rRNAs, and repetitive sequence elements including Alu, and L1 sequences, as well as (b) undesired peptide encoding nucleic acid sequence elements such as mitochondrial RNAs, prokaryotic, and fungal mRNAs. See Examples 18 and 20 at cols. 20-21 and 23. It would have been obvious to one of ordinary skill in the art at the time the invention was made to recognize a peptide of claims 55, 57, and 58 in the nucleic acid sequence of GenBank Accession No. AA236084 in view of the state of the art demonstrated by Edwards et al. because the nucleic acid sequence of GenBank Accession No. AA236084 provides but one extensive continuous open reading frame among the six potential open reading frames, where the EST sequence is identical to the nucleic sequence of SEQ ID NO:1 from position 796 through position 1140, inclusive, and one of ordinary skill in the art could readily and routinely determine that this continuous open reading frame encodes the 114-amino acid region of the amino sequence of SEQ ID NO:2 from position 214 through position 328, inclusive.

Claims 55, 57, and 58 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the human cDNA clone IMAGE:684275 having the GenBank Accession No. AA236014 and published in 1997 by the Cancer Genome Anatomy Project of the National Cancer Institute, already of record, in view of Edwards et al., US 6,222,029, made of record herewith.

Applicant's arguments in the Response filed 3 August 2007 with respect to claims 55, 57, and 58 have been considered but are moot in view of the new ground(s) of rejection. Applicant

suggests that the disclosure of the nucleic acid sequence of the human cDNA in GenBank Accession No. AA236014 cannot be prior art because more than one amino acid sequence may be deduced from the nucleotide sequence of the cDNA. Claims 55, 57 and 58 do not require that a "comprising" polypeptide have any particular size, that it commence with any particular amino acid, or that it have any particular carboxyl terminal amino acid and, indeed, require no more than sequence identity with any 25, or 50, or 100, contiguous amino acids somewhere within SEQ ID NO:2. Edwards et al. demonstrate that at the time the invention was made it was (i) routine to determine the longest continuous open reading frame, and the deduced amino acid sequence thereof, from the six potential open reading frames available in any human EST, and that it was also (ii) routine to exclude from consideration ESTs generated from transcripts isolated from human tissues that correspond to (a) non-coding nucleic acid sequence elements such as tRNAs, rRNAs, and repetitive sequence elements including Alu, and L1 sequences, as well as (b) undesired peptide encoding nucleic acid sequence elements such as mitochondrial RNAs, prokaryotic, and fungal mRNAs. See Examples 18 and 20 at cols. 20-21 and 23. It would have been obvious to one of ordinary skill in the art at the time the invention was made to recognize a peptide of claims 55, 57, and 58 in the nucleic acid sequence of GenBank Accession No. AA236014 in view of the state of the art demonstrated by Edwards et al. because the nucleic acid sequence of GenBank Accession No. AA236014 provides but one extensive continuous open reading frame among the six potential open reading frames, where the EST sequence is identical to the nucleic sequence of SEQ ID NO:1 from position 995 through position 1376, inclusive, and one of ordinary skill in the art could readily and routinely determine that this continuous open reading frame encodes the region of the amino sequence of SEQ ID NO:2 from position 280 through position 407, inclusive.

Claims 55, 57, and 58 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the human cDNA clone of Adams et al. designated EST33924, having the GenBank accession No. AA330056 and published in 1997 by the Institute of Genomic Research, already of record, in view of Edwards et al., US 6,222,029, made of record herewith.

Applicant's arguments in the Response filed 3 August 2007 with respect to claims 55, 57, and 58 have been considered but are moot in view of the new ground(s) of rejection. Applicant suggests that disclosure of the nucleic acid sequence of the human cDNA in GenBank accession No. AA330056 cannot be prior art because more than one amino acid sequence may be deduced from the nucleotide sequence of the cDNA. Claims 55, 57 and 58 do not require that a "comprising" polypeptide have any particular size, that it commence with any particular amino acid, or that it have any particular carboxyl terminal amino acid and, indeed, require no more than sequence identity with any 25, or 50, or 100, contiguous amino acids somewhere

within SEQ ID NO:2. Edwards et al. demonstrate that at the time the invention was made it was (i) routine to determine the longest continuous open reading frame, and the deduced amino acid sequence thereof, from the six potential open reading frames available in any human EST, and that it was also (ii) routine to exclude from consideration ESTs generated from transcripts isolated from human tissues that correspond to (a) non-coding nucleic acid sequence elements such as tRNAs, rRNAs, and repetitive sequence elements including Alu, and L1 sequences, as well as (b) undesired peptide encoding nucleic acid sequence elements such as mitochondrial RNAs, prokaryotic, and fungal mRNAs. See Examples 18 and 20 at cols. 20-21 and 23. It would have been obvious to one of ordinary skill in the art at the time the invention was made to recognize a peptide of claims 55, 57, and 58 in the nucleic acid sequence of GenBank Accession No. AA330056 in view of the state of the art demonstrated by Edwards et al. because the nucleic acid sequence of GenBank Accession No. AA330056 provides but one extensive continuous open reading frame among the six potential open reading frames, where the EST sequence is identical to the nucleic sequence of SEQ ID NO:1 from position 1290 through position 1563, inclusive, and one of ordinary skill in the art could readily and routinely determine that this continuous open reading frame encodes the region of the amino sequence of SEQ ID NO:2 from position 379 through position 469, inclusive.

Conclusion

Claim 63 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Although no particular function is now required for a polypeptide of claim 63, the specification discloses that it has sentrin-specific protease activity.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr Bragdon, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general

nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
17 August 2007

KATHLEEN KERR BRAGDON, PH.D.
SUPERVISORY PATENT EXAMINER